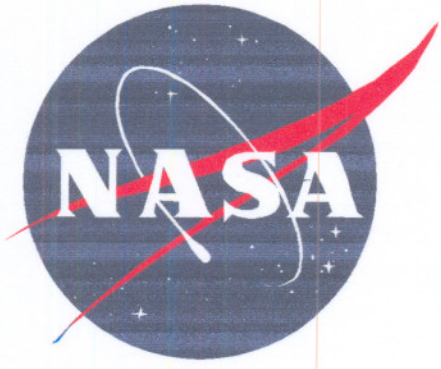
JSC 63828
Revision B

BIOSAFETY REVIEW BOARD
OPERATIONS AND REQUIREMENTS DOCUMENT

Biosafety Review Board
Environmental Factors Branch
Habitability and Environmental Factors Division

July 2007
Rev B: October 2010



National Aeronautics and Space Administration
Lyndon B. Johnson Space Center
Houston, Texas

Biosafety Review Board
Operations and Requirements Document

Environmental Factors Branch
Habitability and Environmental Factors Division
NASA Johnson Space Center

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Revision Log

Revision	Date	Changes
Baseline	7/1/07	Initial Release
Revision A	3/17/08	Added statement "A scanned copy of the revised document will also be posted on the BRB website." To section 1.3
Revision B	10/6/10	Revised section 2.1.2
		Revised Table 1
		Added section 3.3
		Added Appendix E

Biosafety Review Board Operations and Requirements Document

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Table of Contents

Biosafety Review Board
Operations and Requirements Document
Acronym List

ATCC	American Type Culture Collection
BRB	Biosafety Review Board
BSL	Biosafety Level
CDC	Centers for Disease Control and Prevention
ISS	International Space Station
JSC	Johnson Space Center
NASA	National Aeronautics and Space Administration
NIH	National Institutes of Health
PSRP	Payload Safety Review Panel
WHO	World Health Organization

Biosafety Review Board
Operations and Requirements Document

I. Introduction

The mission of the Johnson Space Center (JSC) Biosafety Review Board (BRB) is to provide safety policy and operational-level guidance to the Center and its contractors for in-flight and ground-based activities involving the use of biohazardous materials. Functions of the BRB include developing and monitoring an inventory for onsite biohazardous materials, providing guidelines for systematic inspection of facilities in which biohazardous materials are utilized, and evaluating in-flight and ground-based experiments involving biohazardous materials.

1.1 Purpose

This document establishes requirements for the information required by the BRB to identify and assess biohazardous materials utilized in payload or ground-based experiments. The document also defines the requirements for tracking biohazardous materials that are stored at JSC facilities and the requirements for inspecting JSC facilities utilizing biohazardous materials.

This document supersedes all biological material references in JSC 27472 "Requirements for Submission of Data Needed for Toxicological Assessment of Chemicals to be Flown on Manned Spacecraft".

1.2 Scope

These requirements apply to all payloads that contain biohazardous materials located in the habitable pressurized volume of the ISS or U.S. operated spacecraft such as the Space Shuttle and the Commercial Orbital Transportation System (COTS) Cargo Vehicle. These payloads include, but are not limited to, science payloads, government furnished equipment (GFE), risk mitigation experiments (RMEs), developmental test objectives (DTOs), detailed supplementary objectives (DSOs), short duration bioastronautics investigations (SBDIs), life science experiments, and medical studies. Proprietary formulations are also included with the understanding that the information will be protected from non-essential disclosure. Requirements also apply to vectors such as animals and plants, and non-biological materials such as soil that may harbor biohazardous materials. The requirements in this document do not apply to crew food or personal preference items.

These requirements also apply to any ground-based experiments at JSC facilities involving biohazardous materials and any JSC facilities that store biohazardous materials.

1.3 Authority

The specific provision of the BRB is authorized by JSC Policy Charter JPC 1152.19 (Appendix A) and JSC Policy Directive JPD 5340.1 (Appendix B).

Distribution of this document is controlled by the Chairperson of the BRB at JSC. Revisions will be issued to offices and individuals included on the distribution list. A scanned copy of the revised document will also be posted on the BRB website. Changes to this document will be authorized by the Chairperson of the BRB.

II. Concept of Biosafety

Biological materials are classified as non-hazardous and biohazardous. Biohazardous materials may include bacteria, fungi, protozoa, viruses, cell cultures, recombinant DNA, and others. Plants, animals, and some inanimate objects may also be vectors of biohazardous agents.

2.1 Classifications of Biohazardous Materials

Biohazardous materials are further classified by Biosafety Levels (BSL) as defined in *Biosafety in Microbiological and Biomedical Laboratories* (latest edition). This document was developed and distributed by the U. S. Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH). Biohazardous materials are classified as BSL-1 through BSL-4 risks. BSL classifications can be accessed via the CDC website at www.cdc.gov.

The World Health Organization (WHO) recognizes biohazardous materials and also developed and distributed a document addressing biosafety issues. The *Laboratory Biosafety Manual* (latest edition) developed by the WHO classifies biohazardous materials into Risk Groups ranging from Risk Group 1 through Risk Group 4. Subtle differences exist between the WHO and the CDC/NIH documents but assessment approach and conclusions are compatible. These guidelines are widely used by academia, government, and industry in the U.S. and internationally.

The four BSLs, categorized by CDC/NIH, are described below.

2.1.1 BSL - 1: well-characterized agents not known to consistently cause diseases in healthy adults, and of minimal potential hazard to laboratory personnel and the environment. Example: *Bacillus subtilis*

2.1.2 BSL - 2: agents that pose moderate potential hazard to personnel and the environment (absence of aerosols). Example: *Influenza, Legionella*

2.1.3 BSL - 3: Indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route (applicable to clinical, diagnostic, teaching, research or production facilities). Example: *West Nile Virus, Mycobacterium tuberculosis.*

2.1.4 BSL - 4: Dangerous and exotic agents which pose a high individual risk of aerosol transmitted laboratory infections and life-threatening disease. Example: *Ebola Virus*

The NASA ground-based BSL are identical to those of the CDC/NIH. The BRB has modified the BSLs categorized by the CDC/NIH for in-flight biohazardous materials. The NASA in-flight BSLs are listed in Table 1 and are applicable to all payloads containing biohazardous materials. Table 1 also includes information pertaining to NASA Hazard Levels and NASA Payload Safety Review Panel's Containment Levels.

III. Biosafety Review Process

It is the policy of the BRB that all payloads containing biological materials and all ground-based experiments utilizing biological materials shall be assessed. Each identified biohazardous agent/material shall be assigned a NASA BSL.

3.1 Payload Assessment Criteria

All payloads manifested for flight on the Space Shuttle, International Space Station (ISS), other space vehicle participating in a joint mission involving the Space Shuttle or the ISS, or future U.S. operated spacecrafts such as the Commercial Orbital Transportation System (COTS) Cargo Vehicle are required to undergo a thorough safety assessment. The Payload Safety Review Panel (PSRP) conducts this assessment. The PSRP has charged the BRB to review all biological materials, identify biohazardous materials, and provide a biosafety assessment as part of the overall safety evaluation and report findings to the panel.

Biohazardous materials may include bacteria, fungi, protozoa, viruses, cell cultures, recombinant DNA, and others. Vectors such as plants, animals, and some inanimate objects may harbor biohazardous agents and must be evaluated. Biohazardous agents may be infectious and result in disease or contamination of water and food supplies or the crew environment.

For spaceflight applications, biohazardous materials are defined in Table 1. Because of the unique environment and conditions associated with spaceflight, BSL-2 agents are divided into two classes, BSL-2 (Moderate Risk) and BSL-2 (High Risk) agents. This represents a break from the classification system used by the CDC/NIH guide and the WHO manual. However, because of the microgravity conditions, aerosols of microorganisms can be more of a risk factor than under Earth gravity (1-g). Larger particles and droplets can be suspended as aerosols for much longer than experienced at 1-g. In addition, it can be seen in Table 1 that BSL-3 and 4 agents are not allowed on crewed spacecraft because of the dire health consequences.

Table 1. NASA In-flight Biosafety Levels

	Hazard Levels	BSL	Description	*Levels of Containment/Control
Allowed on ISS	Non-hazardous	1	Agent not known to cause diseases in healthy adults.	1
	Critical	2 (moderate)	Moderate risk agents associated with human diseases. Primary exposure routes include percutaneous exposure, ingestion, and mucous membrance exposure.	2
	Catastrophic	2 (high)	Higher risk agents associated with human diseases. Risk is increased by lower infectious dose, likelihood of aerosolization, larger amounts of agent present, and other factors.	3
Not allowed on ISS	Catastrophic	3	Agents with potential for airborne transmission. May cause life-threatening diseases.	N/A
		4	Agents with high potential for life-threatening diseases. High potential for aerosol transmission of agent with no prophylactic or specific therapy.	N/A

* Level of containment/control is determined by the Payload Safety Review Panel.

3.1.1 Type of Data Required for Payload Assessment

The following information must be provided to the BRB in order to obtain an in-flight payload biohazardous material (s) assessment and approval:

- Contact Information
  - The principal investigator's name, title, affiliation, address, telephone number, and fax number.
  - The contact information for the principal investigator's alternate/backup (if available).
- Payload Information
  - The name of the experiment.
  - The name and acronym of payload (if different than the name of the experiment).
  - The experiment number and acronym.
  - The Shuttle mission number.
  - The International Space Station expedition number.

- The launch vehicle and launch date.
- The return vehicle and return date.
- The in-flight storage and use location.

- Biological Materials Information
  - A detailed description of the experimental protocol.
  - The identification and origin of the biological material (s) to be assessed.
  - Indicate if the biological materials are known human pathogens or contain pathogens.
  - The Biosafety Level (BSL) of the biological material, if known.
  - The maximum concentration of each biological sample and the maximum number of samples.
  - The American Type Culture Collection (ATCC) number (s) for the biological material (s), if known.
  - Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1 and 2, and HIV 1 and 2.
  - The proprietary nature of the biological data.
  - Indicate if animals will be used.

3.1.2 Submission of Data for Payload Assessment

The required data for payload assessment shall be submitted online by filling out JSC Form 713 "In-flight Biohazardous Materials Approval Form" (See Appendix C) via http://microbiology.jsc.nasa.gov/microbrb.htm. It is the responsibility of the submitter to verify the accuracy of the data. Inaccurate data may result in the delay of the assessment process. Questions regarding the submission of the form can be submitted on the BRB page at http://microbiology.jsc.nasa.gov/microbrb.htm.

3.1.3 Payload Assessment Process

Upon receipt of the completed form, the biological materials are reviewed by the BRB or a subcommittee composed of BRB members with expertise specific to the biohazardous materials identified in the payload. Information specific to biosafety assessments of biohazardous materials is used to consult data bases such as the American Type Culture Collection (ATCC) to determine biosafety level of biohazardous material used in the flight payload. The subcommittee factors the available biosafety information with the specifics of the payload on-orbit operations. Mitigating factors may include amount of biohazardous agent, liquid or solid growth medium used, infectivity dose, medical or spacecraft integrity consequences, proposed containment configuration, and others. Such mitigating factors may result in adjustments to the final biosafety level assigned to the biohazardous material. The BRB communicates the NASA BSL determination to the PSRP as part of the overall safety evaluation.

If sufficient information is not made available to the BRB, the NASA In-flight BSL may be elevated to ensure safe conditions for the crew.

The containment of the biohazardous materials is determined by the PSRP. The levels of containment correlates with the NASA BRB BSL assigned to the biohazardous agents.

When two or more biohazardous agents are present in the same payload, the levels of containment required will be driven by the most hazardous (highest BSL) agent included. Under most conditions, BSL-1 agents will require 1 level of containment; BSL-2 (Moderate Risk) agents will require 2 levels of containment; and BSL-2 (High Risk) agents will require 3 levels of containment in the payload design. All final determinations of levels of containment are made by the PSRP.

3.1.4 Handling of Payload Data

At the time when data is submitted to the BRB, the submitter shall designate which data, if any, should be treated as proprietary. Proprietary data will only be disseminated to NASA and/or contractor personnel that perform the assessment. After the flight, proprietary data will be destroyed, except those that were archived by the BRB in restricted access locations.

3.1.5 Timeline of Payload Data Submission

Adherence to the required timelines for submission of the payload data is critical for the BRB to prepare and distribute assessment prior to payload safety reviews. Once the BRB has assessed the biological material and determined the BSL, the BRB will send notification of the completed assessment to the Payload Organization representative and representatives of the appropriate NASA safety panel.

Early submission of the form will enable the BRB to make an early biological assessment, which will help the hardware designer to ensure that planned containment and other built-in safeguards are adequate before final design or construction of the hardware.

It is required that the "In-flight Biohazardous Materials Approval Form" shall be submitted to the BRB no later than L-4.5 months for cargo carriers and ISS elements. A BRB memorandum stating the designated NASA in-flight BSL will be distributed within 3 weeks after all the required information have been received.

3.1.6 Re-flown and Previously Assessed Payloads

An "In-flight Biohazardous Materials Approval Form" must be submitted for each payload experiment containing biological materials whether the materials are being flown for the first time or have previously been flown and assessed.

3.2 Ground-based Experiment Assessment

All ground-based experiments utilizing biological material (s) shall be assessed by the BRB. The BRB will designate a NASA ground-based BSL to each identified biohazardous material. The assessments will enable the principal investigator to ensure that the appropriate facility and personal protective equipments, and proper handling techniques are used when handling the identified biohazardous material (s).
All blood-borne pathogens related exposure assessments requests shall be directed to the JSC Occupational Health Branch.

3.2.1 Type of Data Required for Ground-based Experiment Assessment

The following information must be provided to the BRB in order to obtain a ground-based biological material (s) assessment and approval:

- Contact Information
  - The principal investigator's name, title, organization, affiliation, location, and telephone number.
- Experiment Information
  - The location of the experiment.
  - The names of personnel handling the biological material.
- Biological Materials Information
  - A detailed description of the biological materials and experimental protocol.
  - The origin of the biological material.
  - Indicate if the biological material poses any potential hazards to personnel.
  - Indicate if humans are susceptible to infection by the biological material.
  - Indicate if medical surveillance is required.
  - Indicate if immunization is required.
  - Indicate if animals will be used.
  - Indicate if any type of regulated radiation will be used.
  - The Biosafety Level (BSL) of the biological material, if known.
  - The maximum concentration of each biological sample and the maximum number of samples.
  - The American Type Culture Collection (ATCC) number (s) for the biological material (s), if known.
  - Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1 and 2, and HIV 1 and 2.
  - The proprietary nature of the biological data.

3.2.2 Submission of Data for Ground-based Experiment Assessment

The required data for ground-based experiment assessment shall be submitted online by filling out JSC Form 712 "Biohazardous Materials Approval Form" (See Appendix B) via http://microbiology.jsc.nasa.gov/microbrb.htm. It is the responsibility of the submitter to verify the accuracy of the data. Inaccurate data may result in the delay of the assessment process. Questions regarding the submission of the form can be submitted on the BRB page at http://microbiology.jsc.nasa.gov/microbrb.htm.

3.2.3 Ground-based Experiment Assessment Process

Upon receipt of the completed form, the biological materials are reviewed by the BRB or a subcommittee composed of BRB members with expertise specific to the biohazardous materials identified in the experiment. Information specific to biosafety assessments of biohazardous materials is used to consult data bases such as the ATCC to determine biosafety level of biohazardous material used in the experiment.

The actual risk associated with handling a biological agent depends not only on the nature of the agent, but also on the laboratory manipulations employed during its handling.

When the biosafety assessment is completed, BRB notification stating the designated NASA ground-based BSL will be sent to the principal investigator and the laboratory supervisor.

If sufficient information is not made available to the BRB, the NASA ground-based BSL may be elevated to ensure safe conditions for laboratory workers.

3.2.4 Handling of Ground-based Experiment Data

At the time when data is submitted to the BRB, the submitter shall designate which data, if any, should be treated as proprietary. Proprietary data will only be disseminated to NASA and/or contractor personnel that perform the assessment.

3.2.5 Timeline of Ground-based Experiment Data Submission

It is required that the "Biohazardous Materials Approval Form" shall be submitted to the BRB at least 2 weeks prior to the experiment.

3.3 Recombinant DNA/RNA Experiment Assessment

All ground-based experiments involving recombinant DNA/RNA (rDNA/RNA) shall be assessed by the BRB. The BRB will compile a memorandum detailing the laboratory practices and techniques, safety equipment, and laboratory facilities that are required for the experiment according to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

3.3.1 Type of Data Required for rDNA/RNA Experiment Assessment

The following information must be provided to the BRB in order to obtain a ground-based rDNA/RNA assessment and approval:

- Contact Information
    - The principal investigator's name, title, affiliation, location, and telephone number.
- Experiment Information
    - The location of the experiment.
    - The names of personnel handling the biological material.
    - Funding (whether it's provided by NIH)
- Biological Materials Information
    - A detailed description of the biological materials.
    - The origin of the biological material.
    - The types of vector and the replication competency.
    - The size and nature of inserted sequence.
    - The nature of the encoded materials.

- Indicate if immunization is required.
- Indicate if animals will be used.
- Indicate if any type of regulated radiation will be used.

3.3.2 Submission of Data for rDNA/RNA Experiment Assessment

The required data for ground-based rDNA/RNA experiment assessment shall be submitted online by filling out JSC Form 644 "Recombinant DNA/RNA Approval Form" (See Appendix D) via http://microbiology.jsc.nasa.gov/microbrb.htm. It is the responsibility of the submitter to verify the accuracy of the data. Inaccurate data may result in the delay of the assessment process. Questions regarding the submission of the form can be submitted on the BRB page at http://microbiology.jsc.nasa.gov/microbrb.htm.

3.3.3 rDNA/RNA Experiment Assessment Process

Upon receipt of the completed form, the rDNA/RNA materials are reviewed by the BRB or a subcommittee composed of BRB members with expertise in rDNA/RNA.

When the rDNA/RNA biosafety assessment is completed, a BRB memorandum detailing the laboratory practices and techniques, safety equipment, and laboratory facilities that are required for the experiment according to the *NIH Guidelines for Research Involving Recombinant DNA Molecules* will be sent to the principal investigator and the laboratory supervisor.

If sufficient information is not made available to the BRB, the NASA ground-based BSL may be elevated to ensure safe conditions for laboratory workers.

3.3.4 Handling of rDNA/RNA Experiment Data

At the time when data is submitted to the BRB, the submitter shall designate which data, if any, should be treated as proprietary. Proprietary data will only be disseminated to NASA and/or contractor personnel that perform the assessment.

3.3.5 Timeline of rDNA/RNA Experiment Data Submission

It is required that the "rDNA/RNA Approval Form" shall be submitted to the BRB at least 2 weeks prior to the experiment.

IV. Biosafety Inspection of JSC Laboratories Utilizing Biological Materials

It is the policy of the BRB that all JSC laboratories utilizing biohazardous materials shall be inspected. The Biosafety Inspection is to be conducted by members of the BRB annually.

4.1 Purpose of the Biosafety Inspection

The purpose of the annual Biosafety Inspection is to determine whether JSC laboratories storing/utilizing/disposing biohazardous materials are in conformance with the biosafety guidelines as outlined in the latest edition of "Biosafety in Microbiological and Biomedical Laboratories" published by CDC/NIH and to ensure that laboratory personnel are properly trained and are knowledgeable of the appropriate laboratory techniques, safety procedures, and hazards associated with handling biohazardous agents/materials.

4.2 Biosafety Inspection Checklist

Contact the chairperson, alternate chairperson, or executive officer of the BRB for a complete biosafety inspection checklist. The biosafety inspection checklist is also available for download from the JSC Microbiology Laboratories website at http://microbiology.jsc.nasa.gov/microbrb.htm. It is recommended that laboratory supervisor should review the checklist and correct deficiencies prior to the inspection.

V. Inventory of Biohazardous Materials

It is the policy of the BRB that all JSC laboratories utilizing biohazardous materials shall submit a biohazardous materials inventory annually. Technical monitor and supervisor of the laboratories are responsible for submitting the inventory.

5.1 Submission of Biohazardous Materials Inventory

The purpose of the annual biohazardous materials inventory is to maintain a centralized database where all biohazardous materials data can be stored, queried, and traced by the BRB. The data shall be submitted online via the JSC Microbiology Laboratories website at http://microbiology.jsc.nasa.gov/microbrb.htm.

5.2 Type of Data

The following information must be submitted to the BRB annually for the Inventory of Biohazardous Materials:

- Contact Information
  - The name of the laboratory storing the biohazardous materials.
  - The NASA Technical Monitor of the laboratory.
  - The contract supervisor/manager of the laboratory.
- Location of the Biohazardous Materials
  - The building and room number where the biohazardous materials are stored.
- Biohazardous Materials Information
  - A detailed description of the biohazardous materials.
  - Biosafety Levels, if known.

Appendix A: JSC Policy Charter 1152.19

JSC Policy Charter
JPC 1152.19

EFFECTIVE DATE: _____

EXPIRATION DATE: _____

RESPONSIBLE OFFICE: SA/Space Life Sciences

SUBJECT: Johnson Space Center (JSC) Biosafety Review Board

1. **PURPOSE**. To define the functions and membership of the JSC Biosafety Review Board.

2. **APPLICABILITY**. All JSC employees and contractors.

3. **AUTHORITY**
   a. JSC Policy Directive 5340.1, "JSC Biosafety Review Board."
   b. Occupational Safety and Health Administration, "Occupational Exposure to Bloodborne Pathogens," 2003, 29 CFR 1910.1030.
   c. NSTS/ISS 13830, latest revision, "Payload Safety Review and Data Submittal Requirements for Payloads Using the Space Shuttle and International Space Station."
   d. NSTS 1700.7B, latest revision, "Safety Policy and Requirements for Payloads Using the Space Transportation System."
   e. NSTS/ISS 1700.7B ISS Addendum, latest revision, "Safety Policy and Requirements for Payloads Using the International Space Station."
   f. JSC 27472, latest revision, "Requirements for Submission of Data Needed for Toxicological Assessment of Chemicals and Biologicals to be Flown on Manned Spacecraft."
   g. SSP 50260, latest revision, "International Space Station Medical Operations Requirements Documents".
   h. NPR 1800, "Occupational Health Program Requirements."
   i. JPR 1700, "Johnson Space Center Safety and Health Program Requirements."

4. **REFERENCES**
   a. "Dangerous Goods Regulations Publication," Latest edition, International Air Transport Association.
   b. "Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens, Division of Emerging and Other Communicable Diseases Surveillance and Control," Latest edition, World Health Organization, Geneva.

c. "Laboratory Biosafety Guidelines," Latest edition, Laboratory Centre for Disease Control, Health Protection Branch, Health, Canada.
d. "Laboratory Biosafety Manual," Latest edition, World Health Organization, Geneva.
e. "National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules." Latest edition, U.S. Department of Health and Human Services.
f. Health and Human Services Publication (Centers for Disease Control and Prevention and National Institutes of Health) 93-8395, "Biosafety in Microbiological and Biomedical Laboratories," Latest edition.
g. Code of Federal Regulations-Transportation 49 Parts 100 to 185 and Parts 186 to 199. Latest revision.
h. KHB 1700.7, latest revision, "Space Shuttle Payload Ground Safety Handbook."

5. **CHARTER**. This Board is established to satisfy requirements for appropriate management and use of known and potentially biohazardous materials, including but not limited to:
   a. Microbiological biohazards associated with humans, animals, and plants.
   b. Biohazards associated with biotechnology research and development.
   c. Biohazards associated with space operations and missions.

   And to ensure compliance with applicable standards from the:
   - Department of Labor, Occupational Safety and Health Administration
   - Department of Agriculture
   - Environmental Protection Agency
   - Department of Health and Human Services, Centers for Disease Control and Prevention, and the National Institutes of Health
   - World Health Organization
   - National Aeronautics and Space Administration

   Establishment of the Biosafety Review Board is necessary in the public interest in accordance with International, Federal, State, and local regulatory requirements.

6. **FUNCTIONS.** The JSC Biosafety Review Board shall:
   a. Provide technical expertise for the NASA community, to ensure all biohazardous materials are handled, stored, transported, and disposed of according to regulations.
   b. Provide risk evaluation of biohazardous materials.
   c. Conduct a review of in-flight experiments in accordance with the Payload Safety Review Panel requirements and provide documentation as needed.
   d. Conduct a review of ground-based biological experiments.
   e. Conduct an annual inventory of biohazardous materials stored at JSC facilities.
   f. Conduct an annual inspection of JSC facilities utilizing biohazardous materials.
   g. Review handling, storage, transportation, and disposal of biohazardous materials.

7. **COMPOSITION.** Expertise in health, safety, space life sciences, biological research, and other relevant disciplines shall be represented by the personnel (Civil Servant and Contractors) serving on the Board. The NASA Directorates shall designate the representatives from their respective organizations. The Director of Space Life Sciences shall designate the Chairperson and Alternate Chairperson. Additional members shall be added with approval of the Space Life Sciences Director

as required without amending this Charter. Membership of the JSC Biosafety Review Board includes representatives from the following organizations:

NASA/JSC

- SA/Space Life Sciences Directorate
  - Cell Biologist
- SD/Space Medicine and Health Care Systems Division
  - Flight Surgeon
  - Occupational Health Branch
- SF/Habitability and Environmental Factors Division
  - Chairperson
  - Alternate Chairperson
  - Executive Officer
- SK/Human Adaptation and Countermeasures Division
  - Cell Biologist
- KT/Astromaterials Acquisition and Curation Division
  - Astrobiologist

Space Life Sciences Contract Representatives

- Safety
- Microbiologist

Non-NASA

- Biosafety

8. **MEETINGS**.
Meetings shall be held at the call of the Chair with an agenda furnished. Meetings shall be conducted in accordance with bylaws approved by the Director of Space Life Sciences and the Director of Safety and Mission Assurance. Minutes of the board meetings shall, as a minimum, contain a record of persons present, a description of matters discussed, conclusions reached, action assignments and/or action taken and shall include copies of all reports received, issued, or approved by the Board.

_____

Michael Coats
Director

Distribution:
JDMS Library

Appendix B: JSC Policy Directive 5340.1

JSC Policy Directive

JPD 5340.1

EFFECTIVE DATE: _____

EXPIRATION DATE: _____

RESPONSIBLE OFFICE: SA/Space Life Sciences

SUBJECT: Johnson Space Center (JSC) Biohazardous Materials Protection Policy

1. **POLICY**
   a. It is JSC policy to exercise centralized management over operating procedures that include biohazardous materials to ensure such biohazards are handled, stored, transported and disposed of according to regulations during ground and flight operations.
   b. Introduction of biohazardous materials into JSC laboratories requires the written approval of the JSC Biosafety Review Board (BRB).

2. **APPLICABILITY.** This Policy Directive applies to all organizational elements of JSC and to all contractors and visiting personnel (including but not limited to, all visitors working with biohazardous materials, visiting scientists, students, and technical personnel) working under the administrative management of JSC.

3. **AUTHORITY**
   a. JSC Policy Charter 1152.19, "JSC Biosafety Review Board."
   b. Occupational Safety and Health Administration, "Occupational Exposure to Bloodborne Pathogens," 2003, 29 CFR 1910.1030.
   c. NSTS/ISS 13830, latest revision, "Payload Safety Review and Data Submittal Requirements for Payloads Using the Space Shuttle and International Space Station."
   d. NSTS 1700.7B, latest revision, "Safety Policy and Requirements for Payloads Using the Space Transportation System."
   e. NSTS/ISS 1700.7B ISS Addendum, latest revision, "Safety Policy and Requirements for Payloads Using the International Space Station."
   f. JSC 27472, latest revision, "Requirements for Submission of Data Needed for Toxicological Assessment of Chemicals and Biologicals to be Flown on Manned Spacecraft."
   g. SSP 50260, latest revision, "International Space Station Medical Operations Requirements Documents".
   h. NPR 1800, "Occupational Health Program Requirements."
   i. JPR 1700, "Johnson Space Center Safety and Health Program Requirements."

4. REFERENCES

a. "Dangerous Goods Regulations Publication," Latest edition, International Air Transport Association.
b. "Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens". Latest edition. World Health Organization, Division of Emerging and Other Communicable Diseases, Surveillance and Control, Geneva.
c. "Laboratory Biosafety Guidelines," Latest edition, Office of Biosafety Laboratory Center for Disease Control, Health Canada, Ottawa, Ontario Canada.
d. "Laboratory Biosafety Manual," Latest edition, World Health Organization, Geneva.
e. "National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules, (National Institutes of Health)." Latest edition, U.S. Department of Health and Human Services.
f. Health and Human Services Publication (Centers for Disease Control and Prevention and National Institutes of Health) 93-8395, "Biosafety in Microbiological and Biomedical Laboratories," Latest edition.
g. Code of Federal Regulations, Transportation 49 Parts 100 to 185 and Parts 186 to 199. Latest revision.
h. KHB 1700.7, latest revision, "Space Shuttle Payload Ground Safety Handbook."
i. NPR 1800, "Occupational Health Program Requirements."
j. JPR 1700, "Johnson Space Center Safety and Health Program Requirements."

5. RESPONSIBILITY

a. The Director of Space Life Sciences has the responsibility of developing and implementing policies, procedures, and controls for the use of biohazardous materials at JSC and/or on space missions involving this Center and of securing any licenses or permits required for such activities. In addition, the Director of Space Life Sciences is authorized to establish a JSC Biosafety Review Board, including subcommittees, to assist with these responsibilities, which may be further delegated within the provisions of existing JSC policy and other applicable Federal regulations. The Director of Space Life Sciences shall conduct periodic review of appointments and responsibilities of those appointed to ensure a sound biosafety review program.
b. Supervisors are responsible for ensuring that all personnel whose job entails the use of or exposure to biohazardous materials receive proper orientation and training.
c. All personnel identified by their supervisors as using biohazardous materials are required to attend mandatory safety and health training and adhere to all applicable JSC policies and procedures.
d. JSC Occupational Health Branch, within Space Life Sciences, provides the primary function for institutional health compliance including day to day biosafety issues at JSC.

6. **OBTAINING APPROVAL FROM JSC BIOSAFETY REVIEW BOARD**
   a. Personnel introducing biohazardous materials obtained from any source (e.g., commercial, other research facilities, field samples), to JSC must submit a completed, "Biohazardous Materials Approval Form" (Form 712). Approval must be obtained prior to bringing biohazardous materials on site. Any payload organization submitting a Safety Data Package (SDP) containing any biological material must submit a completed, "In-flight Biohazardous Materials Approval Form" (Form 713), to the JSC BRB.
   b. The BRB shall send a written response to the requester.

7. **METRICS.**
   a. The JSC BRB shall maintain records related to activities concerning biohazardous materials in a database. The laboratory managers shall maintain the baseline information for annual review by the JSC BRB.
   b. Findings of laboratory annual reviews shall be used by the JSC BRB for evaluation of operations and to seek strategies that shall prevent any hazardous or adverse occurrences in laboratories.

_____

Michael Coats
Director

DISTRIBUTION:
JDMS

Attachments:
"Biohazardous Materials Approval Form", JSC Form 712
"In-flight Biohazardous Materials Approval Form", JSC Form 713

Appendix C: JSC Form 713 "In-flight Biohazardous Materials Approval Form"

In-flight Biohazardous Materials Approval Form

Items 1-15 are to be completed by requesting organization (Must be typed):

1. Principal Investigator Name, title and affiliation:	2.Address (building, room number, telephone and fax number):

3a. Name of experiment:

3b. Name and Acronym of Payload (if different than the name of the experiment in 3a):

4. Experiment Number and Acronym (If applicable):

5a. Shuttle Mission Number:

5b. International Space Station Expedition Number:

6a. Launch vehicle:	6b. Launch date:
7a. Return vehicle:	7b. Return date:

8. In-flight Storage Location:	9. In-flight Use Location:
International Partner Concurrence:	International Partner Concurrence:
θ Yes θ No θ Not applicable	θ Yes θ No θ Not applicable

10. Please attach a detailed description of the experimental protocol.
Follow the checklist (A-H) provided below. Answer each letter in the checklist as thoroughly as possible.

Checklist: (to be completed for data submittal)

A. **Provide the identification and origin of biological material.**
B. **Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens.**
C. **Indicate the American Type Culture Collection number (ATCC#), if known.**
D. **Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2.**
E. **Indicate the maximum concentration of each sample.**
F. **Indicate the Biosafety Level (BSL), if known.**
G. **Indicate the maximum number of samples.**
H. **Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe, tray, canister, etc.**

NOTE:
**** Items A and B are intended to be answered using a thorough description.**
**** Items C thru H can be answered in a table format for simplicity (see attached sample table for reference).**

11. Is there any proprietary data? Yes θ No θ If yes, please explain.

12. Will animals be used? Yes θ No θ If yes, please explain. (Include Status of ACUC Approval

13. Will this project utilize any type of regulated radiation? Yes θ No θ If yes, please explain. (Include Status of Radiation User Approval)

14. Name/telephone and fax number of Principal Investigator: **Signature and date:**	**15. Name/telephone and fax number of contact person (an additional person who may provide information):** **Signature and date:**

To be completed by JSC Biosafety Review Board (BRB):

Approved/Disapproved:

Comments:

_____ _____

(Typed Name and Telephone Number of Chairperson) **Date**

JSC Form 713

Appendix D: JSC Form 712 "Biohazardous Materials Approval Form"

Biohazardous Materials Approval Form	
To be completed by requesting organization (all requested information must be typed):	
1. Name, title and affiliation:	**2. Address (building, room number, telephone number):**
3. Description of biohazardous material:	
4. Origin of biohazardous material:	
5a. List any potential hazards to personnel: None **5b. Are humans susceptible to infection by this organism? Yes No** **Is medical surveillance required/recommended? Yes No** **5c. Is immunization required/recommended? Yes No**	
6. Project location: Building(s) and room number(s) to be used for storage, analysis, and disposal:	
7. Name(s) of personnel (scientists) handling materials:	**8. List all other biological research projects that may be involved with this project and may present a risk of cross-contamination:**
9. Describe procedures on attached pages:	
10. Will animals be used? Yes No If yes, please explain. (Status of JSC ACUC Approval)	
11. Will this project utilize any type of regulated radiation? Yes No If yes, please explain. (Status of JSC Radiation User Approval)	
12. Name/telephone number of NASA Technical Monitor: **Signature and date:**	**13. Name/telephone number of Contract Laboratory Supervisor:** **Signature and date:**
To be completed by JSC Biosafety Review Board:	
Approved/Disapproved: **Comments:** _____ _____ **(Typed Name and Telephone Number of Chairperson)** **Date**	

JSC Form 712

Appendix E: JSC Form 644 "Recombinant DNA/RNA Approval Form"

Recombinant DNA/RNA Approval Form

To be completed by requesting organization:

1. Name, title and affiliation:	2. Address (building, room number, telephone number):

3a. Description of biohazardous material:

3b. rDNA □ rRNA □

4. Origin of biohazardous material:

5a. Is the experiment funded by NIH? Yes □ No □
5b. Are any of the collaborators in the experiment funded by NIH? Yes □ No □
5c. Is any of the staff involed in the experiment funded by a NIH scholarship and/or stipend? Yes □ No □

6a. Types of vector (s): _____

6b. If the vector is a virus, does the experiment have the potential to increase the replication capacity of virus?
N/A □ No □ Yes □:_____ (specify)

6c. Use of defective DNA/RNA with Helper virus?
N/A □ No □ Yes □:_____ (specify)

6d. Size of the insert/total genome: _____

6e. Nature of Inserted sequence: _____

6f. Does the inserted gene encode a known oncogene and/or a known toxin?
No □ Yes □:_____ (specify)

6g. Does the inserted gene/viral DNA integrate into the host genome?
No □ Yes □:_____ (specify)

6h. Protein (s) produced: _____

6i. Types of host (s): _____

6j. Would this research alter the host range of the agent?
No □ Yes □:_____ (specify)

6k. Would this research enhance the virulence of the agent, or render a non-pathogen virulent?
No □ Yes □:_____ (specify)

6l. Would this research increase transmissibility of the agent?
No □ Yes □:_____ (specify)

6m. Is the staff trained on the the safe handling and decontamination procedures for this agent? Yes □ No □

6n. Is medical surveillance required/recommended? Yes □ No □

6o. Is immunization required/recommended? Yes □ No □

7. Project location: Building(s) and room number(s) to be used for storage, analysis, and disposal:	
8. Name(s) of personnel (scientists) handling materials:	**9. List all other biological research projects that may be involved with this project and may present a risk of cross-contamination:**
10. Describe experiment procedures in details as an attachment:	
11. Will animals be used? Yes □ No □ **If yes, please explain. (Status of JSC ACUC Approval)**	
12. Will this project utilize any type of regulated radiation? Yes □ No □ **If yes, please explain. (Status of JSC Radiation User Approval)**	
13. Name/telephone number of NASA Technical Monitor: **Signature and date:**	**14. Name/telephone number of Contract Laboratory Supervisor:** **Signature and date:**
To be completed by JSC Biosafety Review Board:	
Approved/Disapproved: **Comments:** _____ _____ **(Typed Name and Telephone Number of Chairperson)** **Date**	

JSC Form 644